

BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The invention listed below is co-owned by an agency of the U.S.

Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for

companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and codevelopment research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

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SUPPLEMENTARY INFORMATION: Technology description follows.

<u>Title of invention</u>: Anti- B-Cell Maturation Antigen Antibodies for Developing Cancer Therapeutics

<u>Keywords:</u> BCMA, Antibody, Immunotoxin, Chimeric Antigen Receptor (CAR), Antibody-drug Conjugate (ADC), Bispecific Antibody, Cancer, Myeloma,

<u>Description of Technology:</u>

Multiple Myeloma is a subtype of leukemia that originates in bone marrow, where normal plasma cells are produced. Although FDA-approved antibody-based therapy is available for other B-cell malignancies, no effective antibody-based therapies are available for MM due to the lack of specific target antigen on MM cells. BCMA (B-Cell Maturation Antigen), is a membrane antigen selectively expressed on mature B-lymphocytes and in all MM cells from patients. Thus, BCMA shows promise as a target for immune-based therapy.

This technology concerns the generation of several monoclonal antibodies against BCMA. These antibodies can be utilized therapeutically in several ways, including as recombinant immunotoxins, chimeric antigen receptors (CARs), antibody-drug conjugates (ADCs), bispecific antibodies, and as unconjugated antibodies. The antibodies can also be use in diagnostic applications. It is important to note that several conjugated immunotoxins using the antibodies of this invention have already exhibited high efficacy against MM cells in recent *in vitro* studies.

Potential Commercial Applications:

- Therapeutic Uses
 - Use as an unconjugated antibody
 - Use as a targeting moiety for immunoconjugates such as CARs, ADCs, immunoconjugates, bispecific antibodies, etc.
- Diagnostic agent for detecting and monitoring BCMA-expressing malignancies

Value Proposition:

- First to market potential There are no current targeted therapeutics for BCMA
- High specificity and binding to BCMA results in less non-specific cell killing,
 therefore fewer potential side-effects for the patient
- Chimeric Antigen Receptor-based therapies have been successful against B-cell lineage cancer; an anti-BCMA CAR represents a highly effective therapeutic candidate

Development Stage:

In-vitro testing

<u>Inventor(s)</u>:

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Intellectual Property:

US Provisional Application 62/255,255 (HHS Reference No. E-010-2016/0-US-

01) filed November 13, 2015 entitled "Anti-BCMA Polypeptides and

Conjugates";

US Provisional Application 62/257,493 (HHS Reference No. E-010-2016/1-US-

01) filed November 19, 2015 entitled "Anti-BCMA Polypeptides and Proteins"

Contact Information:

Requests for copies of the patent application or inquiries about licensing, and codevelopment research collaborations should be sent to John D. Hewes, Ph.D. email: john.hewes@nih.gov or phone: 240-276-5515.

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John D. Hewes

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